REMARKS

Claims 1 - 7 and 21 - 28 are pending in the application. No claims are amended by this response. Applicant hereby applies for a three-month extension of time.

Claims 1 - 7 and 21 - 28 stand rejected over WO 90/09804 ("Zanetti") under 35 USC 102(b). However, applicant respectfully disagrees. Zanetti teaches the use of certain engineered immunoglobulins for the purpose of inducing an immune response to a delivered epitope:

> The present invention is based upon the successful production of novel immunoglobulin molecules having introduced into the N-terminus variable region thereof a novel epitope not ordinarily found in the immunoglobulin molecule used as a starting molecule, such epitopes retain specific reactivity. Preferably such reactivity is characterized by the epitope's ability to stimulate an antigenic response.
> Page 5, lines 8 – 15 of Zanetti (emphasis added).

In fact, Zanetti is concerned mostly with creating a vaccine:

> The present invention is further directed to pharmaceutical compositions containing, as essential pharmaceutical principal, a novel immunoglobulin hereof, particularly those in the form of an administratable pharmaceutical vaccine.
> Zanetti, Page 5, lines 26 – 30.

Examples I and II, the only working Examples in Zanetti, are clearly concerned with generating antibodies to the delivered antigen. For instance, in Example 1, on page 19, it is stated:

> To determine whether the recombinant y_1NANB antibody could be used to induce anti-NANP antibodies, in vivo experiments were performed in rabbits. Two rabbits were immunized with the engineered y1NANP antibody, and two controls received the WT Ig. As indicated in Table 1, infra., as early as 30 days after the first immunization, both rabbits immunized with the y_1NANB antibody, and two controls receive the WT Ig. As indicated in Table I, infra., as early as the 30 days after the first immunization, both rabbits immunized with the y_1NANB antibody produced anti-NANP antibodies detectable by ELISA and RIA.
> Zanetti, page 19, lines 8 – 15.

Pages 19 – 20 go on to discuss an "immunization scheme" with booster injections. Example II is also focused on creating an "antibody vaccine" (see pages 23 – 24).

There are only two brief passages mentioned in Zanetti where it is theorized that the engineered immunoglobulins of Zanetti might be useful in treatments of autoimmune disorders. On page 5, lines 31 – 33, Zanetti states:

> The present invention is further directed to methods useful for building tolerance to certain antigens, including those associated with autoimmune diseases, or for down-regulating hypersensitivity to allergens ...

The Abstract of Zanetti states the following:

> The epitope-containing immunoglobulins are useful in treating such diseases as autoimmune disorders, as the epitope inserted into the binding domain of the immunoglobulin is capable of inducing or preventing sensitization of the host to that epitope.

It is unclear precisely what strategy Zanetti has in mind for use of his engineered immunoglobulins in "building tolerance to certain antigens" or for "downregulating hypersensitivity to allergens." These two passages are the only mention of use of immunoglobulins as taught in Zanetti for treatment of autoimmune disorders. There is no mention of how or in what strategy the immunoglobulins of Zanetti would be used to prevent sensitization of the host to an epitope. It is probable that Zanetti is referring to displacement of self-pathogenic peptides and not engagement of autoreactive T cells because displacement of self-pathogenic peptides was a favored strategy at that time. There is no teaching in Zanetti which would lead one to the conclusion that it is the same mechanism of the claimed invention. Thus, it would not be accurate to state that Zanetti is a proper 102(b) reference over the claimed invention which requires "downregulation of autoreactive T cells." Nothing in Zanetti mentions "T cell receptor agonist for presentation on the surface of said antigen presenting cell ... thereby resulting in downregulation of autoreactive T cells" for the purpose of treating autoimmune disorders. To be a proper 102(b) rejection, every element of the claim must be present must be present in the prior art reference. Richardson vs. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d, 1913, 1920 (CAFC 1989); MPEP 2131. Clearly, not every element of claims 1 – 7 and 21 – 28 are

taught in Zanetti. Nor would claims 1 – 7 and 21 - 28 be obvious under 35 USC 103(a) over Zanetti in that there is no teaching or suggestion in Zanetti of the claimed invention, that is, the mechanism by which the fusion protein of the claimed invention downregulates autoreactive T cells to treat autoimmune disorders.

Applicant respectfully requests withdrawal of the rejection and allowance of the present application. If there are any questions, applicant's attorney can be reached at the telephone number stated below.

Respectfully submitted,

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